JUL 2 3 2003

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

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Contact Person: Norbert Küchemann

Position/Title: Sales Manager

Date of Preparation: May 19, 2003

(2) **Trade Name:** VECTOR, VECTOR Plus; SCALAR, SCALAR Plus; Mono Level CPAP devices with Humidifier Option

Common/Classification Name: VENTILATOR, CONTINUOUS, NON-LIFE-SUPPORTING; HUMIDIFIER, RESPIRATORY GAS (Humidification on Plus Models only)

Product Code(s): MNS, 21 CFR §868.5895.
BTT, 21 CFR §868.5450

Class: Class II

(3) **Predicate Device(s):** Fischer and Paykel HC200 Nasal CPAP with Heated Humidifier (K973161)

Reason for Submission: New Device

(4) **Description of Device:**

Hoffrichter SCALAR and VECTOR CPAP devices provide mono-level CPAP treatment levels over the clinician settable range of 3 to 18 cmH_2O.

All devices are constructed on a common platform, including case, mechanical and pneumatic components, operator panel, and electronic control system. A 2 x 16 character display with keys on the operator panel provides the user with displayed information about the treatment level as well as access to menus for time/date, ramp and other functions.

VECTOR's power supply automatically supply adapts to regional mains voltage (115 to 230 VAC), whereas SCALAR is set to the region (115 or 230 VAC) by rear panel switch.

Models with a Plus designation include integrated heated humidification. An adjustment dial permits the user to select the humidification level. Moisture contacting materials in the breathing circuit meet biocompatibility requirements.

Treatment pressure is measured as close as possible to the patient mask by means of a measuring tube integrated into the therapy tubing. This maximizes accuracy and control of pressure and minimizes losses due to the therapy delivery circuit.

Hoffrichter CPAP devices have a user selectable ramp function, which starts with a reduced pressure and slowly increases to the treatment pressure to make it more comfortable to fall asleep. The user can adjust the ramp time from 0 to 60 minutes. A mask test may be initiated at the full treatment pressure before the ramp begins to check for mask leaks.

Accessories include treatment tubing with integrated measurement tube and headgear. Commercially available masks and swivels are specified.

A serially connected remote control device, the MULTI 20, supplied for clinician use during patient tests, emulates operator panel functions.

Hoffrichter CPAP devices are prescription use devices, and are not intended for life supporting or life sustaining applications.

(5) **Intended use:**

Obstructive sleep apnea (OSA) is a condition caused by closing of the upper airway during sleep. The uvula and soft pallet collapse on the back wall of the upper airway, and when the tongue moves back, the airway is temporarily sealed, causing disruptions in normal respiration and sleep.

Continuous Positive Airway Pressure (CPAP) is an effective treatment for OSA. CPAP devices treat the condition by supplying a constant positive pressure to the airway, most commonly via the nasal passages, in order to prevent the collapse of the soft tissue of the uvula and soft palate during sleep.

Indications for Use:

The Scalar, Scalar Plus, Vector, and Vector Plus devices are for treatment of obstructive sleep apnea (OSA) in adult patients weighing at least 30 kg. These devices are not intended for use with ventilator-dependent patients.

The Scalar, Scalar Plus, Vector, Vector Plus devices provide continuous positive airway pressure. The Scalar Plus and Vector Plus devices provide humidification of the air delivered to the patient.
Indications for use are the same as the predicate device. Both devices state CPAP treatment for OSA in non ventilator-dependent adult patients, with available humidification.

(6) **Technological Characteristics:**

The Hoffrichter CPAP devices employ the same technological characteristics as the predicate device. Both employ a computer controlled blower system which is attached via tubing to a swivel and nasal mask to deliver a prescribed mono-level CPAP treatment to a patient over the range 3 to 18 cmH_2O. Both employ a hotplate type design to heat a water reservoir to add humidification.

The predicate device sets pressure by a manual blower speed adjustment. The Hoffrichter CPAP devices employ pressure measurement at the mask via a measurement hose integrated into the breathing hose. This enables improved pressure control and accuracy by the Hoffrichter CPAP devices.

(b) (1) **Non-Clinical Tests Submitted:**

The Hoffrichter CPAP devices were tested in accordance with applicable standards for medical device Electrical Safety, Electromagnetic Compatibility, Heated Humidifiers, Shock and Vibration, and Environmental Temperature and Humidity. The CPAP devices passed all of the tests.

Static and dynamic pressure testing was performed in comparison with the predicate device. In all cases the Hoffrichter CPAP devices met or exceeded the performance specifications of the predicate device.

Software across all platforms was verified to requirements and validated to meet intended use by pressure testing and event testing.

(2) **Clinical Tests Submitted:** (None)

(3) **Conclusions from Tests:**

As described in (b)(1) above, all of the testing demonstrated that the Hoffrichter CPAP devices are as safe and effective as and perform as well or better than the predicate device, the Fisher and Paykel HC200.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2003

Hoffrichter GmbH
C/O Mr. Stephen H. Gorski
Consultant
Imagenix, Incorporated
S65 W 35739 Piper Road
Eagle, WI 53119

Re: K014074
Trade/Device Name: Hoffrichter *Scalar*, *Scalar Plus*, *Vector*, and *Vector Plus* CPAP Devices
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator
Regulatory Class: II
Product Code: BZD
Dated: May 19, 2003
Received: May 22, 2003

Dear Mr. Gorski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for, Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K014074

Device Name: Hoffrichter Vector, Vector Plus, Scalar, Scalar Plus: CPAP with Humidifier Option

Indications for use:

The Scalar, Scalar Plus, Vector, and Vector Plus devices are for treatment of obstructive sleep apnea (OSA) in adult patients weighing at least 30 kg. These devices are not intended for use with ventilator-dependent patients.

The Scalar, Scalar Plus, Vector, Vector Plus devices provide continuous positive airway pressure. The Scalar Plus and Vector Plus devices provide humidification of the air delivered to the patient.

Caution: Federal law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K014074

Prescription Use X OR Over the Counter Use ____
(Per 21 CFR801.109)

(Optional Format 1-2-96)